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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,252	03/21/2001	Nancy D. Hanson	180.0003 0103	6198

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EXAMINER
LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/814,252	HANSON ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,7-11,17-21,24-27,30-38 and 49-57* is/are pending in the application.

4a) Of the above claim(s) *1,2,4,5,7-10,17-21,24-27,30-38 and 49-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,56 and 57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8/01 and 9/01*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group IV, claims 11, 56, and 57, and a pair of primers consisting of SEQ ID NO: 32 and 33 in the response filed on December 17, 2002 is acknowledged. The traversal is on the ground(s) that: (1) "the invention as claimed can be readily evaluated in one search without placing undue burden on the Examiner. That is, all the claims are do interrelated that a search of one group of claims will reveal art to the others."; (2) "[W]ere restriction to be effected between the claims of Groups I to XIII, a separate examination of the claims in these 13 groups would require substantial duplication of work on the part of the U. S. Patent and Trademark Office."; (3) "for restriction to be effected between the claims in Groups I to XIII, it would place an undue burden by requiring payment of 12 separate filing fee for examination of the nonelected claims, as well as the added costs associated with prosecuting 13 applications and maintaining 13 patents."; (4) "the method for identifying a beta-lactamase in a clinical sample (independent claim 17), and claims including the elected PSEI, PSE/, or CARR3 family beta lactamase and related primers depending therefrom (claims 27 and 38)" should be examined with Group IV; (5) "although the Examiner indicated prior art that could be used to reject claim 17, Group XIII, including claims 17, 37, and 38, should be examined with Group IV, as these claims recite and/or encompass the primer pair recited in the claims of Group IV." ; and (6) "[A]pplicants elect, with traverse, the following primer pair per the species election." since "it is understood that (a) the requirement will be withdrawn upon the finding of an allowable genus; and (b) any species withdrawn from consideration will be transferred to the elected subject matter

unless it is found patentably distinct from the elected or allowed claims. Applicants traverse on the grounds that the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the Examiner.".

The above arguments have been fully considered and have not been found persuasive toward the withdrawal of the restriction requirement nor persuasive toward the relaxation of same such that Groups I to XIII will be examined together or Groups V (claims 11, 56, and 57) and VIII will be examine together. First, the examiner notes that, in fact, applicant elects Group V (claims 11, 56, and 57), not Group IV, for the examination since Group IV includes claims 8, 9, 54, and 55 and does not include claims 11, 56, and 57 that is elected by applicant (see page 1, first paragraph of applicant's response to restriction requirement). Second, applicant agreed with applicant that Groups I to XIII are related each other. According to MPEP 808.02, "the related inventions as claimed are shown to be distinct under the criteria of MPEP § 806.05(c) - § 806.05(I), the examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following:" (1) a separate classification; (2) a separate status in the art when they are classifiable together; and (3) a different field of search. Since, as shown in previous office action, Groups I, II, III, IV, and V require different searches, there will be a search burden on the examiner to search these groups together and a separate examination of the claims in these 13 groups would not be substantial duplication of work on the part of the U. S. Patent and Trademark Office. Since Groups I, II, III, IV, and V and Groups VI, VII, VIII, IX, X, XI, XII, and XIII have different classifications and are related as product and process of use wherein the product as claimed can be used in a materially different process of using that product

such as a hybridization assay, the restriction is proper. Relating to applicant's request to combine Groups V and VIII (combining claims 11, 56, and 57 with claims 17, 37, and 38), since Groups V and VIII have different classifications and the product in Group V as claimed can be used in a materially different process of using that product such as a hybridization assay, the restriction is proper. Third, "requiring payment of 12 separate filing fee for examination of the nonelected claims, as well as the added costs associated with prosecuting 13 applications and maintaining 13 patents." is not the reason for the restriction. Fourth, since the examiner has clearly indicated that the restriction for nucleotide sequences should not to be construed as a species election in previous office action, applicant's argument on species election is not persuasive and the requirement will not be withdrawn upon the finding of an allowable genus or any species withdrawn from consideration will not be transferred to the elected subject matter. Furthermore, according to MPEP 803.04, since each nucleotide sequence is structurally unrelated and represents an independent and distinct invention, they will be subjected to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Therefore, the requirement is still deemed proper and is therefore made FINAL and claims 11, 56, and 57 will be examined.

Priority

2. The examiner notes that applicant claims the benefits of provisional applications

60/102,181 and 60/121,765, and an earlier application, 09/407,818 in the first sentence of the specification. Since the application 09/407,818 now is US Patent No. 6,242,223, applicant is required to update the status of the application 09/407,818.

Sequence Rules Compliance

3. The original filed sequencing listing has complied with Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Claim Objections

4. Claim 56 is objected to because of the following informalities: the phrase "beta-lactamase nucleic acid of interest" in (a) of the claim should be "a beta-lactamase nucleic acid of interest".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Arlet *et al.,* (FEMS Microbiology Letter, 82, 19-26, 1991).

The claimed invention is drawn to a primer. Claim 11 requires that a primer is selected from the group of SEQ ID NO:32, SEQ ID NO:33, full complement of SEQ ID NO:32 or SEQ ID NO:33, and partial complement of SEQ ID NO:32 or SEQ ID NO:33.

Arlet *et al.,* teach construction by polymerase chain reaction and intragenic DNA probes for three main types of transferable beta-lactamases (TEM, SHV, CARB). They disclosed two SHV primers OS-2 and OC-1 (see Table 2 in page 21). Since OS-2 is a partial complement of SEQ ID NO:33 (see sequence alignment below, matched bases have bold letters), claim 11 is anticipated by Arlet *et al.*.

5' -**GCGAC**TGTGATG**TA**TAAACG - 3' (SEQ ID NO:33) (claim 11)
5' -**AGCAGG**GCGACAA**AT**CCCGCG-3 (OS-2) (taught by Arlet *et al.,*)

Therefore, Arlet *et al.,* teach all limitations recited in claim 11.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to

the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arlet *et al.,* as applied to claim 11 above, and further in view of Fluit *et al.,* (WO91/08305, published on June 13, 1991).

The claimed inventions are drawn to a diagnostic kit. Claim 56 requires that a diagnostic kit for detecting a PSEI, PSFA, or CARB3 family beta-lactamase comprising: (a) at least one primer pair capable of hybridizing to a beta-lactamase nucleic acid of interest; (b) a positive and negative control; and (c) a protocol for identification of the beta-lactamase nucleic acid of interest. Claim 57 further limits the kit in claim 56 and requires that at least one of the primers in the kit is selected from the group consisting of SEQ ID NO:32, SEQ ID NO:33, full complement of SEQ ID NO:32 or SEQ ID NO:33, and partial complement of SEQ ID NO:32 or SEQ ID NO:33.

The teachings of Arlet *et al.,* have been summarized previously, *supra.* Arlet *et al.,* also teach to amplify probes of TEM, SHV, and CARB beta-lactamases and use these probes to hybridize with reference strains with known beta-lactamases and clinical strains with unknown beta-lactamases (see Table 1 in pages 20 and 21 and left columns in pages 23 and 24).

Regarding claim 56, since two SHV primers OS-2 and OC-1 are used to amplify a SHV beta-lactamase probe in the method of Arlet *et al.,*(see Table 2 in page 21, left column in page 22,

and Figure 1 in page 23), OS-2 and OC-1 are a primer pair capable of hybridizing to a beta-lactamase nucleic acid of interest wherein the SHV beta-lactamase gene is a beta-lactamase nucleic acid of interest as recited in (a) of the claim because these primers hybridize with SHV beta-lactamases during the process of amplifying the SHV beta-lactamase probe. Since the results from colony hybridization assay show that No. 49 of E. Coli strain K12 has a known SHV beta-lactamase gene (SHV-5) and No. 50 of E. Coli strain K12 does not have a SHV beta-lactamase gene, (see Table 1 in page 21), Nos. 49 and 50 of E. Coli strain K12 are positive and negative controls of a SHV beta-lactamase respectively as recited in the claim. Since the method of Arlet *et al.,* includes amplification of beta-lactamase probes by PCR and identification of beta-lactamases in clinical strains by a hybridization assay, and are used to identify SHV beta-lactamases in clinical strains (see Table 1 in pages 20 and 21, right column in page 22, and left column in page 24), the method of Arlet *et al.,* is a protocol for identification of the beta-lactamase nucleic acid of interest wherein the SHV beta-lactamase gene is a beta-lactamase nucleic acid of interest as recited in (c) of the claim. Although two SHV primers OS-2 and OC-1 are not used to detect a PSE1, PSE4, or CARB 3 family beta-lactamase, the limitation "detect a PSE1, PSE4, or CARB 3 family beta-lactamase" has not been given patentable weight because it occurs in the preamble. It is known that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA

1951). Applicant is required to add this limitation into content of claim 56 in order to overcome the rejection.

Regarding claim 57, OS-2 is a partial complement of SEQ ID NO:33 as recited in the claim (see above rejection under 35 USC 102).

Arlet *et al.*, do not disclose a bacteria diagnostic kit as recited in claim 56.

Fluit *et al.*, do teach a bacteria diagnostic kit (see pages 24 and 25).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have organized the components and method taught by Arlet *et al.*, into a kit because the method for identifying a beta-lactamase in a clinical sample using PCR was known at that time the inventions were made and the kit format was utilized not only to assemble a variety of different reagents together but ensure the quality and compatibility of the reagents. One having ordinary skill in the art at the time the invention was made would have been motivated to assemble reagent (s) of biotechnology methods into a kit in order to obtain the above discussed advantages, thus resulting in instant kit recited in claims 56 and 57 . One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to combine these prior art together because the kit would provide a convenient, efficient, economical way to practice the method of Arlet *et al.*

Conclusion

9. No claim is allowed.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
March 31, 2003